Mental Health Drug Workgroup
Meeting Minutes
September 16, 2005

OLD BUSINESS

Dr. Thompson began the meeting with a safety tip and introductions from attendees and telephone conferencing members.

The meeting's agenda required some changes. Mary Montgomery had a family emergency and was unable to present the evidence-based review for gabapentin us for bipolar II, and Peter Lukevich informed Dr. Thompson that he had no information to update the work group concerning DOC continuation of care activities.

The minutes from the August 19, 2005 meeting were approved with two clarifying additions. The corrections will read: (*corrections are in bold type.)*

- Page 2, "The clinical experts agreed with HRSA's position that NEW **ANTIDEPRESSANT** drugs can be obtained after the client has tried and failed or is intolerant to at least two preferred drugs at appropriate dose and duration."
- Page 2, "Feedback regarding **OFF LABEL USE"of anticonvulsants-** *(replacing Neurpathic Pain)*

Mr. Miles requested that the minutes from the 8/19/05 be corrected to read differently. He will be sending verbiage to Jonell Blatt. She will include his clarifications as an Addendum to the minutes of the September 16, 2005 meeting. This additional verbiage will expand on the statement in the 8/19/05 that "The drug companies were opposed to any restrictions related to new mental health drugs."

Mr. Miles also expressed concern about the criteria that is established by clinical staff with reference to new drugs coming onto the market that have not YET been reviewed by the OHSU. Mr. Miles shared that the Prior Authorization criteria placed on these new drugs does not meet the intent of SB6088.

Dr. Thompson explained that the P&T committee can have discussions about these drugs if the group is presented with data. Any discussion would focus on 1) being more effective, 2) being safer, 3) and less costly. However, Medicaid FFS still can only offer these drugs under the Prior Authorization program because they aren't on the PDL at that "snapshot in time." If the timing is such that the new drugs come onto the market after the OHSU starts the reviews, the new drug will not be included in the report. Drug companies are encouraged to send all data related to their drugs to the OHSU for review.

Dr. Thompson asked that the workgroup thoroughly review the letter to interested party that was requested by Senator Prentice (document attached to the workgroup emails). This letter was written to clarify many of the questions being discussed. The contents of the letter was reviewed and approved by an AAG.

Marc Avery asked the workgroup to move forward with the agenda items due to the fact that the discussion is really about agreeing to disagree.

Peter Lukevich stated that we wanted his advocacy group to send letters to the legislature that supports the use of new drugs without the tried and failed Prior Authorization criteria.

NEW BUSINESS

Atypicals - Metrics for FFS Medicaid Clients

Dr. Childs presented the ADSA antipsychotic demographics and Dr. Bredin felt it was "good news". The majority of these clients were age 35-59. There is a 50/50 split between dual eligible and blind/disabled. 89% of these clients were living at home. Nat Miles talked about ensuring that outcomes are studied. Roger Jackson and Marcy Avery shared their clinical experience with dosing and prescribing.

Judy Hall talked about Mental Health data available for outpatient services. Dr. Thompson mentioned the possibility of an Epidemiology study.

Dr. Childs led the presentation and discussion about her document called "Two or More Atypical Antipsycotics Used Concurrently". It was agreed to identify what type of data sorts the workgroup would like to see from ACS on Atypicals. There was agreement to include NH data. The following data pulls were identified as being helpful to the clinical members of the workgroup.

- Duplicate therapy of atypicals with atypicals
- Duplicate therapy of atypicals with typical antipsychotics, Metaclopromide, beta blockers, anticholinergics and atypicals (neurologic side effects)
- Diabetic meds and atypicals (metabolic syndrome)
- Dosing of combination atypicals
- Hospitalization/ ER visits versus 1,2,3,4,5 atypicals in combination.

It was also agreed that Dr. Childs will DRAFT a grid for atypicals like the one she did for SSRIs. Additional discussions about the grid, how it could be designed to work, and what elements needed to be considered took place between Sharon Farmer, Marc Avery, Jeff Thompson, and June Bredin.

Discussion concerning the outcome of TD antidepressant began with the questions "did it change behavior?" TD antipsychotic starts in December – would like to effect MMA. CMS recommends 30 days continuation of mental health drugs by the Prescription Drug Plans providing drugs for Medicare dual eligibles. Mark Avery asked if a survey would be appropriate and Dr. Thompson recommended against a survey after receiving complaints following the antidepressant survey.

Dr. Childs presented the data showing the number of clients that received three continuous months of combination therapy of Risperdal Consta with other oral atypicals. The FDA labeling was reviewed recommending three weeks of overlap while the injectable Risperdal was absorbed and therapeutic blood levels were being achieved. Dr. Jackson said that prescribers are still trying to learn how to use Risperdal Consta and may be using the oral for breakthrough.

Medicare Part D

- CMS will require PDPs to cover.
- Questions needing answers about how providers will know that the client is in the Medicare Program.
- How will Spend-down work in dual eligibles? – Clients will loose their Medicaid coverage after January 2006.
- Workgroup would like data that would give us an estimate of people this program will impact.

Next Steps:

1. October 7th. – Invited guests to review and discuss "dear interested party" letter.
2. Atypicals will be reviewed at P&T Committee in February 2006.
3. Siri will draft a prescribing matrix for atypicals.
4. ACS will provide atypical data according to the data elements identified at this meeting.
5. Medicare PartD will continue to be a standing agenda item discussion.

ADDENDUM 1

Dear Fellow Workgroup Members,

Let me apologize for not making last week's meeting. I was in Omaha helping my mother transition back to home following knee replacement surgery and the last meeting started when the Workgroup started. Moms come first, thanks for understanding.

I am attaching an amended copy of the minutes from 8/19/2005 with my comments which I hope are useful and I hope are reflected in the update version of the minutes. Obviously we would welcome any additional comments.

Bill Struyk

Mental Health Drug Workgroup - DRAFT
1:00 – 4:00
Meeting Minutes
August 19, 2005

To-Do and Workgroup Agreements

Agreed - include Part D Medicaid as an agenda item each month.
Dr. Thompson will send out information about “taper time” – evidence -based
Agreed - Put the taper on the website plus the taper criteria
To-Do - The duplication of atypical data will be reviewed and reported on by the clinical and reported back to the group by January. (My notes indicate that the Workgroup needs to make these decisions by 12/31/2005. Is this the only decision facing the Workgroup with this timeline?)
Agreed - September one meeting and then a meeting with Doug and Duane for a clarification about intent of legislation.
Agreed - October - start meeting twice per month. One will be drug focus and the other is on process
Agreed - It would be excellent to have a "top 1,000" clients using mental health services, including drugs. We could coordinate a great deal of care by using the same model as the Narcotic Review Project with Medicaid clients receiving mental health drugs and services.

Safety

Dr. Thompson thanked everyone for the support given to the Narcotic Review Project and presented a demographics matrix to provide an overview of the program. Doug Porter, Health and Recovery Services Assistant Secretary, wants to see the narcotic's review continue and the top 320 clients has been forwarded to Ken Stark for review and potential Substance Abuse Treatment expansion to these clients. The October briefing for Narcotic Review will attempt to include an explanation of why 22% of prescribers indicate that they have never seen the client.

Old Business

Dr. Thompson reviewed the calendar of events.

Peter Lukevich stated that some clarification is needed to the Explanation of New Agents Document and that previous minutes should reflect there is a difference between what Dr. Childs and Dr. Thompson have said about this topic. At one time Dr. Thompson said these drugs are covered, but later Dr. Child's reminded Dr. Thompson about the tried and failed policy.

Dr. Thompson explained the central issue is clinical rationale and therefore at least two preferred drugs need to be tried and failed or the patient has intolerance to them prior to receiving authorization for a non-preferred drug. (A new drug not studied by OHSU or the P&T Committee is considered non-preferred by HRSA and is neither TIPable nor DAWable. The following is a highlight of the continued discussion:

- Jeff Graham followed that new drugs that are not part of the OHSU report are not reviewed by P&T, so the committee cannot make recommendations for the drug to go on the PDL. Therefore, new drugs are not:
  - Not subject to therapeutic interchange,
  - Not subject to DAW by Endorsing Prescribers, and
  - Not preferred

- The drug companies were opposed to any restrictions related to new mental health drugs. (While I can only speak for Johnson and Johnson, we are opposed to any restrictions other than those authorized by SB 6088. To say we are opposed to any restrictions is not accurate.)

- The Advocates (NMAI and Partners in Crisis) were also opposed to any restrictions.

  - Jim Adams and Peter Lukevich need further explanation why endorsing prescribers don't have rights to prescribe without PA and want the agency to review the refill process on NEW drugs so they don't have to be on PA with a tried and failed 2 drugs process. Nate Miles and Bill Struyk thought the intent of SB6088 was different. SB6088 carved out Mental Health drugs for refills. Peter Lukevich wants an AG's interpretation. (My notes indicate that HRSA indicated that they have an AGO and they will bring it to this meeting. Dr. Thompson, could you please forward this to me? Thanks.)

- Dr. Breden stated that from a clinical point of view PA is a reasonable process to justify clinical rationale for the use of NEW STARTS for new drug. For new starts, it should be tried and failed or intolerant to at least two preferred drugs at appropriate dose and duration before a non-preferred drug is authorized. –The P&T committee does call out specific drugs that can't be interchanged.

- The clinical experts agreed with HRSA's position that NEW drugs can be obtained after the client has tried and failed or is intolerant to at least two preferred drugs at appropriate dose and duration.

Dr. Thompson explained that three state agencies agree to this process, but he will set up a meeting for Jim Adams, Peter Lukevich, and Nate Niles and Bill Stnuyk to discuss 1) Refills, 2) Endorsing providers, and 3) OHSU without P&T committee with Doug Porter and Duane. In addition, Dr. Thompson will reword the last paragraph of the ENDP document. The revised Explanation of New Drugs document will be presented at the next meeting.

New Business

Continuation of Care DOC update- Peter Lukevich was invited to the table with Pierce County Jail for the participation to develop a process for the use of electronic records. There were reps at the meeting as well as RSN. Peter referred to the actions as "little steps but positive steps".

Feedback from Dr. Childs for anticonvulsants – Call lines are flooded. The PA criteria for anticonvulsants are on the website.
http://fortress.wa.gov/dshs/maa/pharmacy/MHworkgroup/PriorAuth.html

Feedback regarding Neuropathic Pain - Sharon Farmer shared that with respect to the Medicaid changes, she has been hearing a lot from prescribers around the state about the task of transitioning clients off the four anticonvulsants whose use is now restricted. Many of the comments have to do with the difficulties in identifying the affected clients and getting them in to discuss options. Other comments are simply fears that any alternative will be less effective. Also, many people are struggling with pharmacies that seem not to know what is going on.

Dr. Thompson will send out the evidence-based information about taper times and will post it on the website. DMM staff will offer 68 days and consider medical justification for a longer period of time. It is not necessary for DMM to know the detail of the taper. Every request for anticonvulsants receives a 30 day fill even if denied, so clients have the time to appeal the denial.

Dr. Childs shared that the refill provision of SB6088 is working very well on the Antidepressants PDL July statistics show only a 2% shift to preferred drugs. Market shares of each drug (preferred and non-preferred) essentially stayed the same due to the "continuation of therapy" provision.

Most Topamax is off-label use, so there will be a form developed for the prescribers to use. This Topamax form will be sent out for the workgroup's information prior to the next meeting. (In the interests of full disclosure, Topamax is a Johnson and Johnson product. My notes from the meeting are very specific, Dr. Thompson stated that in his **opinion most Topamax use is off-label. There was no data so this should read, HRSA "feels, suspects, etc." until confirming data is offered.**

Nate Miles asked about outcome measures and Dr. Thompson explained that the Narcotic Review data would be an excellent model for Mental Health. Community trials do not show benefit because there are too many variables. However, the top 1,000 clients using mental health resources by cost across Medicaid Fee-for-service would most likely represent multiple providers, multiple drugs, multiple ER visits, and multiple hospitalizations.

ADDENDUM 2

Jonell,

I don't know if you got this as it was still in my draft mailbox. However, here is the language that I would like to have inserted into the minutes of the meeting.:

Some of the patient advocacy goups and various companies, voiced their concern that the department was not abiding by the promise of s.b. 6088, that was made during the legislative session.

The promise guaranteed to grant "dispense as written" authority to all endorsing prescribers for all "non-preferred" medications. There was no mention of a third class of medicines being created and labeled "non-reviewed"

Thanks for you help with this. Nate